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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,055	03/26/2004	John B. Cline	1626-309	7598

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EPSTEIN DRANGEL BAZERMAN & JAMES, LLP
60 EAST 42ND STREET
SUITE 820
NEW YORK, NY 10165

EXAMINER

BOGART, MICHAEL G

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/811,055

Applicant(s)

CLINE, JOHN B.

Examiner

Michael G. Bogart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Withdrawal of Allowability

The indicated allowability of claims 35-58 is withdrawn in view of the newly discovered reference(s) to Bar-Shalom (WO 90/07311 A1). Rejections based on the newly cited reference(s) follow.

Claim Rejections – 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-58 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 35 includes the limitations “recess”, “recess defining means”, “stoma covering means” and “means for defining said recess”. These limitations are not present in the specification of the instant application.

Claims 36-58 are rejected because they depend from claim 35 and thus lack enablement for the above described limitations.

Claim 46 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 46 provides for the use of the device of claim 35 for use with a pressure limiting means, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 35-39, 41, 44 and 46-56 are rejected under 35 U.S.C. § 102(b) as being anticipated by Bar-Shalom (WO 90/07311 A1).

Regarding claim 35, Bar-Shalom teaches an ostomy device capable of sealing a stoma said device comprising recess defining means (16); means (10, 11) for securing said recess defining means (16) to the body (12) proximate the stoma (13); and stoma covering means (10, 11, 14), situated externally to the body (12), over the stoma, within said recess defining means (16), said recess defining means (16) defining, with said stoma covering means (10, 11, 14), a

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recess (area under stoma defining means (16)) capable of being pressurized to press said stoma covering means (10, 11, 14) against the stoma (13)(see figure 2, infra).

Regarding the functional limitations, apparatus claims must be structurally distinguishable from the prior art. MPEP § 2114. If the prior art discloses structure that can function according to the limitations of the claims, then the prior art meets the claims.

Regarding claim 36, Bar-Shalom teaches the stoma covering means (10, 11, 14) comprises a flexible member (14).

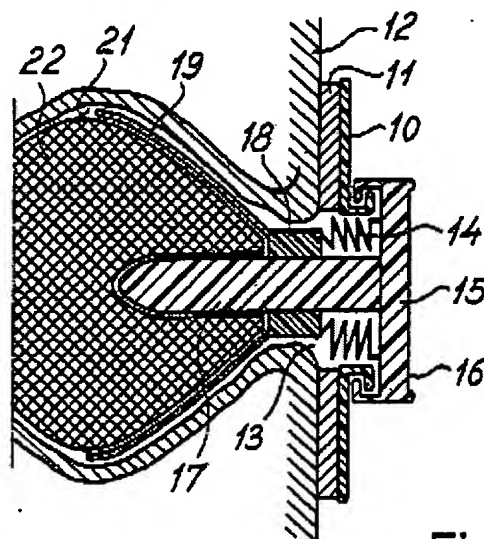
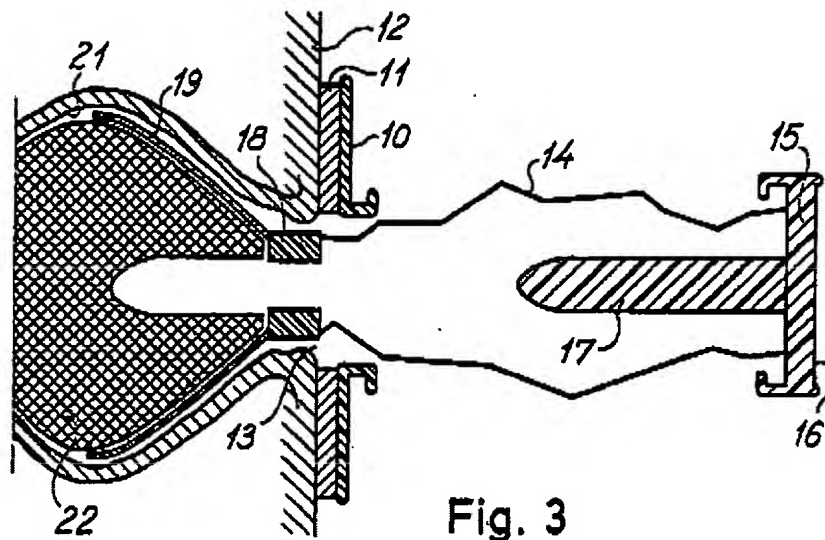


Fig. 2

Regarding claim 37, Bar-Shalom teaches a stoma covering means (10, 11, 14) having an upper edge fixed to the interior of said recess-defining means (16)(see figure 2).

Regarding claim 38, Bar-Shalom teaches a means (16, 19) for pressurizing the recess.

Regarding claim 39, figure 3, infra shows an open configuration of the device where fluid (atmospheric air) is permitted to enter the recess.



Regarding claim 41, Bar-Shalom teaches a that the recess defining means is a pump means (it can be moved back and forth in a reciprocating manner, it can be pressed against receptacle (14) to increase the internal pressure thereof.

Regarding claims 44 and 46, Bar-Shalom teaches a means (15) for applying and/or limiting external pressure on the stoma (it can be pressed into place by hand, and pressure placed thereupon can be limited by hand.

Regarding claims 47 and 48, Bar-Shalom teaches an open configuration that allows venting and filtration of the recess defining means (16)(page 8, lines 18-21)(figure 3).

Regarding claim 49, Bar-Shalom teaches a second recess, the small gap between recess defining means (16) and stoma covering means (10, 11, 16). Bar-Shalom also teaches a filter means (page 8, lines 18-21).

Regarding claims 50 and 51, Bar-Shalom teaches removable means (10, 11) for engaging and adhering the recess defining means (16) to tissue (12) surrounding a stoma (13).

Regarding claims 52-56, Bar-Shalom teaches a collapsible concertina-like waste collection means (14) comprising a pouch (see figure 2) having its upper end connected to a securing means (10, 11, 16).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.

In the event the examiner is not available, the Examiner's supervisor, Tatyana Zalukaeva may be reached at phone number (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300 for formal communications. For informal communications, the direct fax to the Examiner is (571) 273-4933.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-3700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Bogart
12 July 2006

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

